Regulation of Clinical Research Involving Stem Cells

Regulation of Clinical Research Involving Stem Cells: Towards the Construction of a Regulatory Model for Argentina Learning from the Experiences of the United Kingdom

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Rapporteurs
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Summary

This workshop represented the first international interdisciplinary meeting of experts and stakeholders in a process that is intended to culminate in the adoption of a stem cell or broader biosciences research governance scheme in Argentina. It was attended by over 50 participants, including scientists and physicians, academics, and policy-makers and advisors. The emphasis of this workshop was to consider the United Kingdom experience in stem cell regulation, to explore options for an Argentine model, and to map future actions.

Presentations

On 29 November 2007, Dr. Lino Barañao, Director of the Agency for the Promotion and Science & Technology (now Minister of Science & Technology), welcomed the participants, followed by Fabiana Arzuaga, Argentine Stem Cell Commission and University of Buenos Aires.

Professor Graeme Laurie, Director of SCRIPT, the AHRC Centre for Research on Intellectual Property and Technology Law, University of Edinburgh, indicated that the objective of the workshop was to identify key elements in stem cell regulation, and to explore options for establishing an optimal regulatory approach for Argentina. As a preliminary step in the overall process, the workshop would address the state of art of the science, lessons from abroad, and the role of public engagement.

Dr. Paul de Souza, CSO, Roslin Cells Ltd., and Senior Research Fellow, University of Edinburgh, outlined his background as a developmental biologist, and explained the mechanics and difficulties of deriving therapeutic grade human embryonic stem cells.

Mr. Hugh Whittall, Director of the Nuffield Council of Bioethics, outlined the UK's liberal and facilitative regime, and drew on his own experience of working with the Human Fertilisation and Embryology Authority (HFEA). He highlighted the importance of consent to that regime, the role of the HFEA and Parliament in ongoing engagement with the science as it evolves, and the importance of the research purposes criteria to the operability of the UK regime. After noting some of the problems with the UK regime (most notably its complexity and fragmentation, its numerous influences, and continued disagreement over core issues), he recommended that Argentina needs to talk, consult and engage, be flexible, and horizon-gaze, and thereby generally create a supportive environment for good science to flourish.

Mr. Shawn Harmon, Research Fellow at InnoGen and SCRIPT, University of Edinburgh, reiterated the importance of engagement to regulatory creativity and public acceptance. He also echoed the general value of an integrated governance approach with clear processes based on an explicit statement of guiding principles. He went on to outline his empirical research project, "Governing Emerging Technologies: Social Value and Stem Cell Regulation in Argentina" (ESRC Award No. RES-000-22-2678).

Dr. Pablo Argibay, Hospital Italiano, noted that Argentina experienced 21,000 heart attaches per annum, a fact which made both preventative and post-event treatment very important for Argentine healthcare. He highlighted the importance of the Instituto Argentino de Transplante de Organos Tejidos y Celulas (INCUCAI) to work in this area, but noted the many gaps in the governance of clinical conduct and trials, and the importance of the international context (including direction found in the EU Clinical Trials Directive). He suggested that the level of evidence required for approval of stem cell therapies is an issue of key importance for researchers and clinicians, and one that is currently very unclear.

Dr. Fernando Pitossi, Fleni Hospital, together with his research team, is conducting genetic manipulation to get better function from stem cells. He spoke about his pride in working in this area, but noted the many uncertainties of the existing governance setting.

Dr Armando Perichon, indicated that a total absence of research regulation in Argentina led to the rather quick establishment of INCUCAI, which regulates the transplantation of organs, tissue and cells into human patients. Created in 2007 by Resolution, and with very little debate, he suggested that its remit was not broad enough, and that the separate and non-binding work of the ethics committee is a particular problem.

Dr. Ana del Pozo, Banco de Sangre de Cordon Umbilical, outlined a recent cord blood banking initiative and attempts at its governance, drawing on the international and Spanish experiences. She emphasised that cord blood banks are a "public good" needing strong protection, particularly around standards, so that the common good could be promoted. She recommended that regulation should be the same whether an organisation (in the cord blood banking or other biomedical settings) is private or public, and international standards should be drawn on.

Dr. Inés Pertino, Argentine Ministry of Health, stated that many and diverse interests have to be addressed together with the political objective of promoting science, that national laws are probably the best way to proceed, but that formulating a regulatory framework is not easy. The existing regime is full of holes, but work is progressing on Good Clinical Practice guidelines, accreditation for ethics committee membership, and provision of information (on consent, vulnerability, research and international standards) through the internet.

Debates and Reports

On 30 November 2007, the participants divided into three groups which reported as follows:

- **Public Perception:** Chaired S. Harmon, this group highlighted the importance of language (which can be an ethical issue) in encouraging debate around stem cell activities. Whether addressing stem cell sourcing or research purposes, invested stakeholders need to talk to publics and build a culture of communication; this can only be done through the cooperation of universities, research centres, and academics/scientists. This needs to start at the level of values and progress from there. It was noted that power groups in society play an important part in handling/filtering knowledge and constructing truth, so invested stakeholders need to build their dialogues around the biological status of the subject matter, and must be careful to temper their promises concerning the deliverables (short and medium term in particular) of science. It was noted that Argentina is probably hindered by its lack of sociological and philosophical work in this area (as compared to the UK which has a longer track record of involving the public in policy-making).

- **Regulation:** Chaired by H. Whittall, this group explored the role and responsibilities of INCUCAI, which has a role in health delivery under the Ministry of Health. However, it is not clear that it has authority over, and no one is sure what to do about, the lives of stem cells. This group emphasised the value of regulation, the importance of biological understandings informing the debate, and the absolute need for communication and understanding between institutions so that products and processes can travel along the innovation (and regulatory) pipeline with confidence. It was determined that transparency should be a key guiding value, but that other social values need to be recognised and play a part in the discussion if public benefits are to be realised.

- **Science:** Chaired by P. de Souza, this group identified the public-private divide and the research-therapy divide and emphasised that a new regime must be aware of the different (and overlapping) needs within each setting. Current Ministry of Health institutions (INCUCAI, which addresses transplantation, and ANMAT, which addresses ethics in public institutions) have divided and unclear responsibilities, and trajectories in science are causing greater confusion and potential for diffusion and tension. The complexity and fragmentation is heightened by the existence of other relevant institutions, such as CONICET under the Ministry of Science. Grey zones exist regarding authority over the all-important ethical oversight issues, including consent, coercion, standards, etc. (particularly as materials move through the system and from the remit of one institution to the next), the role of international standards, the position of private (as opposed to public) entities, and the role of publication. It is currently clear that the regulatory regime should be blind to the public/private distinction, and that different but very clear standards must be articulated for research and therapy (and materials should not be able to jump from one stream to the next).

Summation / Conclusions

Dr. Lino Barañao thanked everyone for participating. With respect to the messages that came out of the meeting, he thought that those relating to consultation were particularly important, for the future operation of both public and private entities in this field. However, he exhibited caution, suggesting that public consultations conducted too early – before the right information or the right amount of information is yet available – could be damaging, particularly to larger, more established enterprises which are concerned about reputation. Ultimately, he agreed that consultation can help to inform public information campaigns, and therefore public policy in this field.

Next Steps

The rapporteurs would work closely with attendees and others to produce policy biefings and reports on the meeting and to determine how matters should proceed from here. A further meeting would be held in 2008 to consider other experiences of regulation and reform, drawing in particular on the UK's experience with the Human Tissue Authority and reforms due for the Human Fertilisation and Embryology Authority.